Fax:949-713-8206 Jul 6 2004 7:57 P.13

Application No.: 10/052,329 Amdt dated: July 6, 2004

APPLIED MEDICAL

Reply to Office action of: April 8, 2004

#### **EXHIBIT A**

PTO-103P

(Rev. 8-99) PROVISIONAL APPLICATION FILING RECEIPT



in the property of the UNITED STATES DEPARTMENT OF COMMERCE Patent and Trademark Office ASSISTANT SECRETARY AND COMMISSIONER OF PATENTS AND TRADEMARKS Washington, D.C. 20231

APPLICATION NUMBER	FILING DATE:	GRP A	RT UNIT	FIL	FEE REC'D	ATTORNEY DOCKET NO.	DRWGS	TOT CL	IND CL
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RICHARD L MYERS ESQ 26051 MERIT CIRCLE SUITE 103 LAGUNA HILLS CA 92653

Receipt is acknowledged of this Provisional Application. This Provisional Application will not be examined for patentability. Se sure to provide the PROVISIONAL APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION when inquiring about this application. Fees transmitted by check or draft are amplied to collection, "Please verify the accuracy of the data presented on this receipt. If application is noted on this Provisional Application Filing Receipt with the changes noted thereon. If you received a "Notice to File Massing Parts of Application, "Please submit any corrections to this Filing Receipt with your reply to the "Missing Parts Notice." When the PTO Parts Notice "In this application, please submit any corrections to this Filing Receipt with your reply to the "Missing Parts Notice." When the PTO provisional Application will automatically be abandoned twelve (12) months after its filing date and will not be subject to revival to restore it to pending status beyond a date which is after twelve (12) months from its filing date.

CHARLES C. HART, HUNTINGTON BEACH, CA; SAID (C.) HILAL, COTO DE CAZA, CA.

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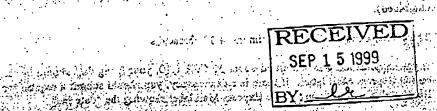
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Docket: RA-1828-AL

### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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Fax:949-713-8206

Date of Deposit: August 30,1999

I hereby certify that the following documents, as identified below, are being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 C.F.R. § 1.10 on the date indicated above and are addressed to the Box Provisional-Patent Applications, Assistant Commissioner for Patents, Washington, D. C. 20231:

- 1. Provisional Application Cover Sheet;
- 2. Verified Statement Claiming Small Entity Independent Inventor;
- 3. Verified Statement Claiming Small Entity Small Business Concern;
- 4. Specification (three (3) pages);
- 5. Informal drawings (eight (8) sheets);
- 6. Check No. 0589 71 in the amount of \$75.00; and
- 7. Return-receipt postcard.

Each of the above-identified documents is enclosed herewith.

Respectfully submitted,

Gabia Pakstvs

Applied Medical Resources Corporation

26051 Merit Circle, Suite 103 Laguna Hills, CA 92653 Telephone (949) 582-6120 Facsimile (949) 582-6123

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Addressed for use through 04/11/96, CAIB 0651-0037
Patent and Trademate Office: U.S. DEPARTMENT OF COMMERCE

#### PROVISIONAL APPLICATION COVER SHEET

This is a request for filing a PROVISIONAL APPLICATION under 37 CFR § 1.53 (b)(2).

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			INVENT	OR(S) / AF	PPLICANT	(3)	`			
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[ ] Additional inventors are being named on separately numbered sheets attached hereto.

P.20

Docket No. RA-1828-AL

Applicant or Patentee: Hart & Hilal

APPLIED MEDICAL

To be Assigned

Serial or Patent No.: Filed or Issued:

Herewith

Title:

SUTURE CLINCH WITH TRACTION ENHANCEMENT

### VERIFIED STATEMENT (DECLARATION) CLAIMING SMALL ENTITY STATUS (37 C.F.R. \$\$ 1.9(f) and 1.27(b))-INDEPENDENT INVENTOR

(37 C.F.R. §§ 1.9(f) and 1.27	
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s a small business concern under 57 C 3 1.5(-)	e assigned, granted, conveyed, or licensed or am under an vey, or license any rights in the invention is listed below:
*NOTE: Separate verified statements are requestion having rights to the invention averring to their	uired from each named person, concern, or organization relatives as small entities. (37 C.F.R. § 1.27)
FULL NAME: <u>APPLIED MEDICAL RESOURCES (</u> ADDRESS: <u>26051 Merit Circle, Suite 103, Lagun</u> [ ] INDIVIDUAL [x] SMALL BUSINESS	CONCERN [] NON-PROFIT ORGANIZATION
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CHARLES C. HART	SAID HILAL
Signature of Inventor	Signature of Inventor
Date:	Date:

Fax:949-713-8206

Applicant or Patentee: Serial or Patent No.: Hart & Hilal To be Assigned

Filed or Issued: Title: Herewith SUTURE CLINCH WITH TRACTION ENHANCEMENT

Docket No.: RA-1828-AL

# VERIFIED STATEMENT (DECLARATION) CLAIMING SMALL ENTITY STATUS (37 CFR §§ 1.9(f) & 1.27(e))—SMALL BUSINESS CONCERN

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I have by declare that I am:	
I hereby declare that I am:  1 the owner of the small business co	ncern identified below.
the owner of the small business co	ncem identified below.  ncem empowered to act on behalf of the concern identified below.
[x] an official of the small business co	
NAME OF SMALL BUSINESS CONCERN:	APPLIED MEDICAL RESOURCES CORPORATION
NAME OF SMALL BUSINESS CONCERN:	26051 Ment Circle, Suite 103, Laguna Hills, California 92653
ADDRESS OF SMALL BUSINESS CONCERN:	
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I hereby declare that the above-identified small business	ness concern qualifies as a small dualities concern qualifies as a small dualities concern including those of its affiliates, does not exceed
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having rights in the invention is listed below and no	less concern are not exclusive, each individual, concern are not exclusive, each individual, concern the inventor, or individual to the invention are held by any person, other than the inventor, and a 37 C.E.R. & 1.9(c) if that person made the invention, or by any
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# SUTURE CLINCH WITH

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## Background of the Invention

## Field of the Invention

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This invention relates generally to surgical clips and clamps, and clinches adapted for use with sutures.

## Discussion of the Prior Art

In the surgical environment, clips and clamps have been used for removably holding two objects in close proximity. These objects may be tissue or surgical devices such as sutures. Clips and clamps may be of the variety disclosed and claimed by Applicant in U.S. provisional patent application serial no. 60/040,655, filed March 10, 1997, and entitled "Surgical Clips and Clamps" Suture clinches of the past are well-represented by Applicant's U.S. patent application serial no. 09/082,495, filed May 21, 1995, and entitled "Suture Clinch". Both of these applications are incorporated herein by reference. In the latter regard, a metal clinch is stamped from a sheet of metal and preformed to operate with a clinch applier. The two free ends of a suture are disposed within the clinch, which is slid down the suture ends until a tight suture is achieved. Then the applier is activated to reform the clinch binding the suture ends into a fixed relationship.

In the case of the metallic clinches, the metal-to-suture interface tends to provide a high coefficient of friction that initially inhibits the sliding step of the process. Ultimately, the metalto-suture interface may provide a lower coefficient of friction than that desired to lock the suture ends in a fixed relationship.

## Summary of the Invention

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In accordance with the present invention, a coating is provided on the clip, clamp, or clinch in order to facilitate one or more of the steps in its operation. With respect to the suture

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clinch, the coating is contemplated which would initially facilitate the sliding step by providing a reduced coefficient of friction with the sutures. Another type of coating might provide an increased coefficient of friction with the sutures, thereby facilitating traction-enhancement during the locking step. More than one coating may be applied to facilitate an initial stage, as well as an ultimate stage of operation.

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Any coating applied to a suture clinch would tend to function as an occlusive cushion to inhibit abrasion between sharp edges and comers of the clinch and the suture material. For traction-enhancement, any material can be used as a coating to produce an increased coefficient of friction with the suture material. In a preferred embodiment, the material chosen is identical to that of the suture material, since similar or identical materials normally exhibit increased frictional resistance to slipping. A more compliant material might be chosen for the traction-enhancement coating in order to increase the area of contact between the clinch and the suture. By increasing the area of contact, elevated compressive pressures need not be applied to securely hold the suture.

The traction-enhancement coating might also be selected to enhance the holding ability with a reabsorbable suture. This permits those portions of the suture distant from the clinch to be reabsorbed, while the suture in the clinch is protected from the absorption process. In preferred embodiments, the traction-enhancing coating includes plastics such as polypropylene or polyethylene.

A lubricious coating could be applied to facilitate the sliding of the clinch along the suture ends. In this case, a reduced coefficient of friction is desirable. A coating of hydrophilic or hydrophilic-hydrophobic material is contemplated to provide the desired lubricity. In a further embodiment, the clinch is coated with two layers of material in a laminate. The first layer is coated on the metallic clinch to provide traction-enhancement. The second layer is coated on the first layer. Initially, the second layer contacts the suture and provides the desired lubricity for sliding the clinch into place. With the hydrophilic coating, moisture is attracted to provide the desired lubricity. As the second layer is oblated by movement of the suture during the sliding step, the first substrate is exposed and ultimately compressed against the suture in the locking step. Alternatively, the second layer may be displaced by the compression of the clinch upon the

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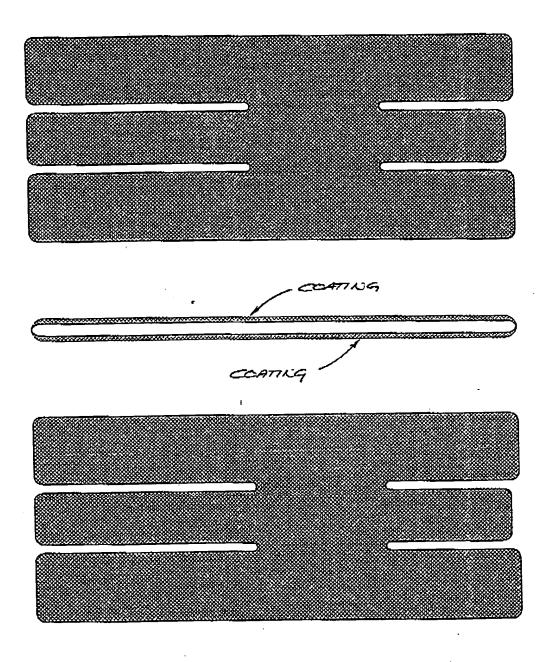
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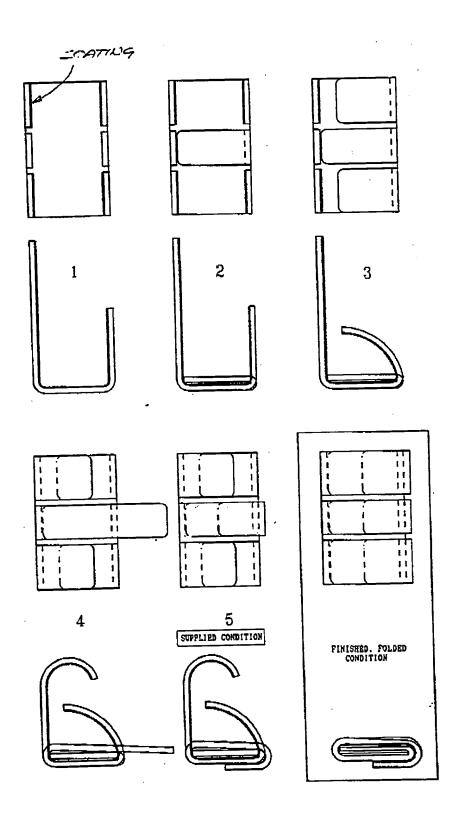
suture. In either case, once the clinch is operatively disposed in its desired position, the first traction-enhancing coating engages the suture ends to lock the suture.

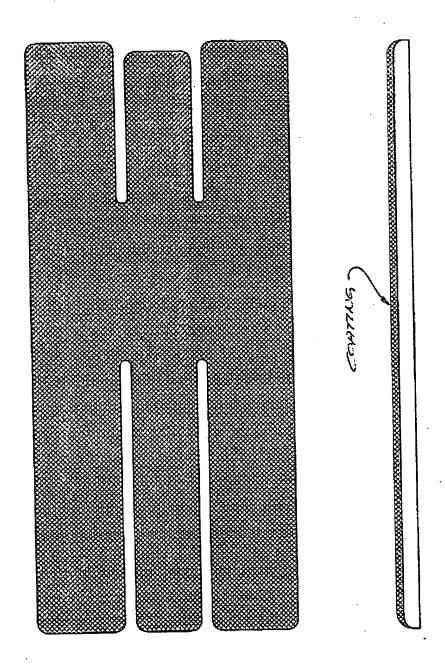
The coatings can be applied in accordance with any known method for coating objects.

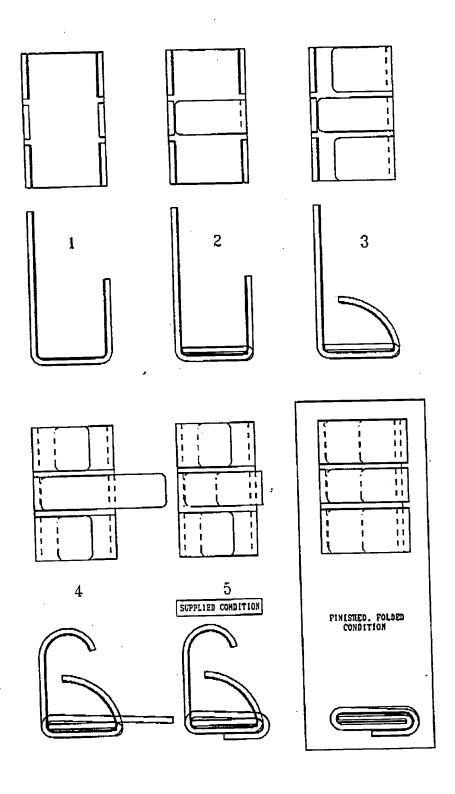
Dip-coating is initially contemplated, but dispersions, solid castings, insert moldings, and spraying may also be appropriate. The coatings can be separately formed and adhered to the metallic base in a further process. Typically, the laminate or coating will be applied to the clinch while it is in the flat-formed condition.

The patent applications referenced above are incorporated herein by reference. The associated drawings (copies attached) are merely representative of any type of clip, clamp, or clinch configuration in the prior art.









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